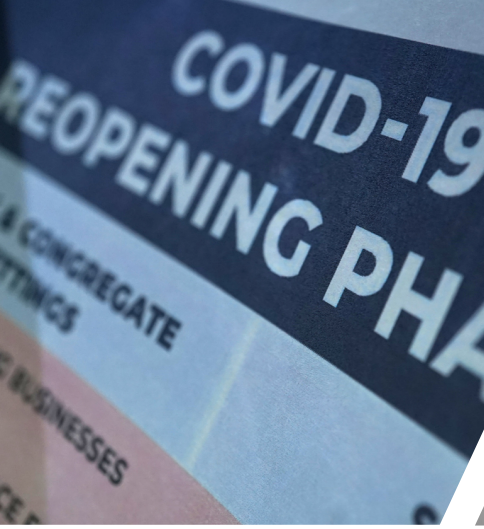

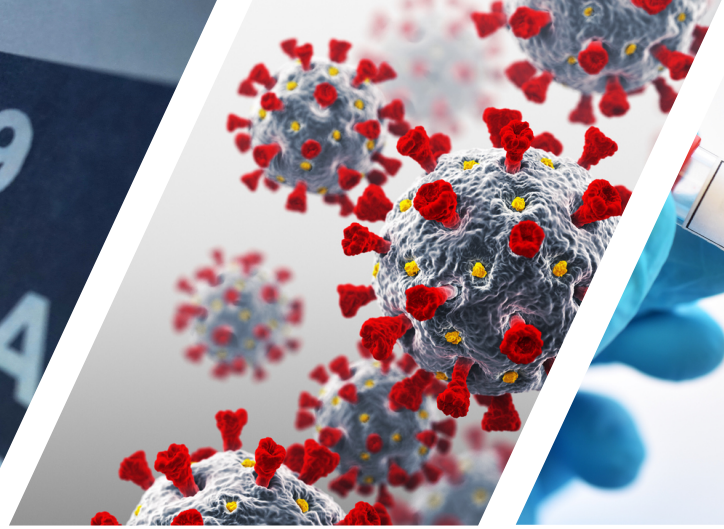

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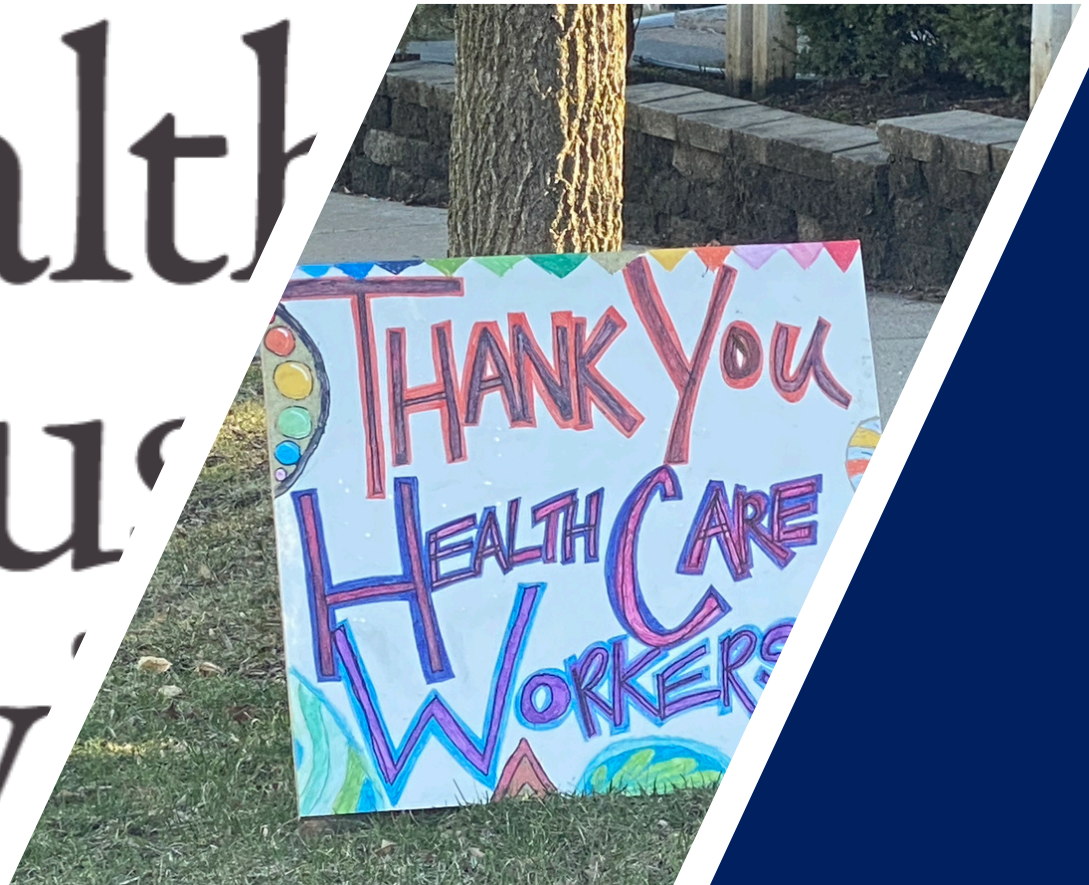


Issue # 195

Monday, October 26, 2020

COVID-19 Report

Highlights

- Vaccine Update
  - **Last week, AstraZeneca and Johnson & Johnson each received the go-ahead to re-start Phase 3 clinical trials of their Covid-19 vaccines**
  - There are four Phase 3 trials underway in the U.S., with BioNtech/Pfizer and Moderna joining AstraZeneca and JNJ; Worldwide, twelve potential vaccines are in Phase 3 trials, with a projected 432k participating volunteers
  - **BioNTech/Pfizer are expected to be the first to apply for Emergency Use Authorization (EUA)in the U.S. - perhaps by mid-November**
  - **With the number of potential vaccines and the rapid pace of clinical trials, many anticipate that a vaccine could be ready for widespread distribution by Q2-Q4 2021. This would represent a 12-18 month timeframe from discovery of cause of a virus to vaccine deployment. By comparison, this process typically requires 10+ years and a $500+ million investment**
  - In addition to the sheer number of potential vaccines (at least 145 are in the pipeline), government efforts are accelerating the development and approval process. In the U.S., Operation Warp Speed (OWS) is the multi-agency federal effort to de-risk the financial investment for companies involved and to fund a ramp-up of manufacturing capacity even before any vaccine receives approval
  - Among the impediments to success of a vaccine(s) in achieving herd immunity will be consumer participation in being vaccinated. In the U.S. **a recent survey indicated that 1-in-3 Americans might not agree to be vaccinated. Chief among their reasons were fear of side effects and doubts of vaccine effectiveness**
- Forecasted Cases and Deaths
  - Dozens of academic and research organizations currently prepare forecasts of Covid-19 cases and deaths in the U.S. On a weekly basis, Covid-19 Forecast Hub compiles these and prepares a composite forecast for the CDC. This composite forecast has been reasonably accurate in short-term forecasts (up to 4 weeks)
  - **The composite forecast suggests a stabilization in both cases and deaths during the next four weeks (cases stable all four weeks; deaths rising slightly the next three weeks, then declining in week four)**
- The weekend was a rough one for Covid-19 cases and deaths in the U.S.
  - **There were more new cases detected this past weekend than on any weekend during the pandemic**
  - **The 7-day new infection rate per capita increased for the twenty-third consecutive day. This rate is now only fractionally lower than its mid-July peak**
  - Thirty states are experiencing the highest 7-day infection rates per capita that they have experienced at any point during the pandemic; Montana, North Dakota, South Dakota and Wisconsin's current rate is higher than that experienced by any state at any time during the pandemic
  - **The 7-day average rate of daily deaths has now increased on 8 of the past 10 days (although it declined yesterday). The current rate is higher than it was at any time from September 19-October 23**
- Inpatient Covid-19 census is an increasing concern in many states yet, there are several encouraging signs
  - On a same-day, prior-week basis, inpatient Covid-19 census increased for the thirty-second consecutive day; the current census is just less than 70% of its mid-July peak
  - **Twenty states are at or near the highest Covid-19 census they have experienced since the pandemic began. Among heavily-populated states, however, most are well below their peak - Ohio being the lone exception**
  - **Still, while this census is increasing, it is not keeping pace with the growth in new cases**
  - **Further, even those persons requiring hospital care are less likely to require intensive care or ventilators, than was the case earlier in the pandemic**
  - Lastly, we are not seeing increases in the % of ER visits due to either Covid-19 or the flu. Notably, **we are now in week four of the official flu season and this year's experience is trailing each of the past five years**

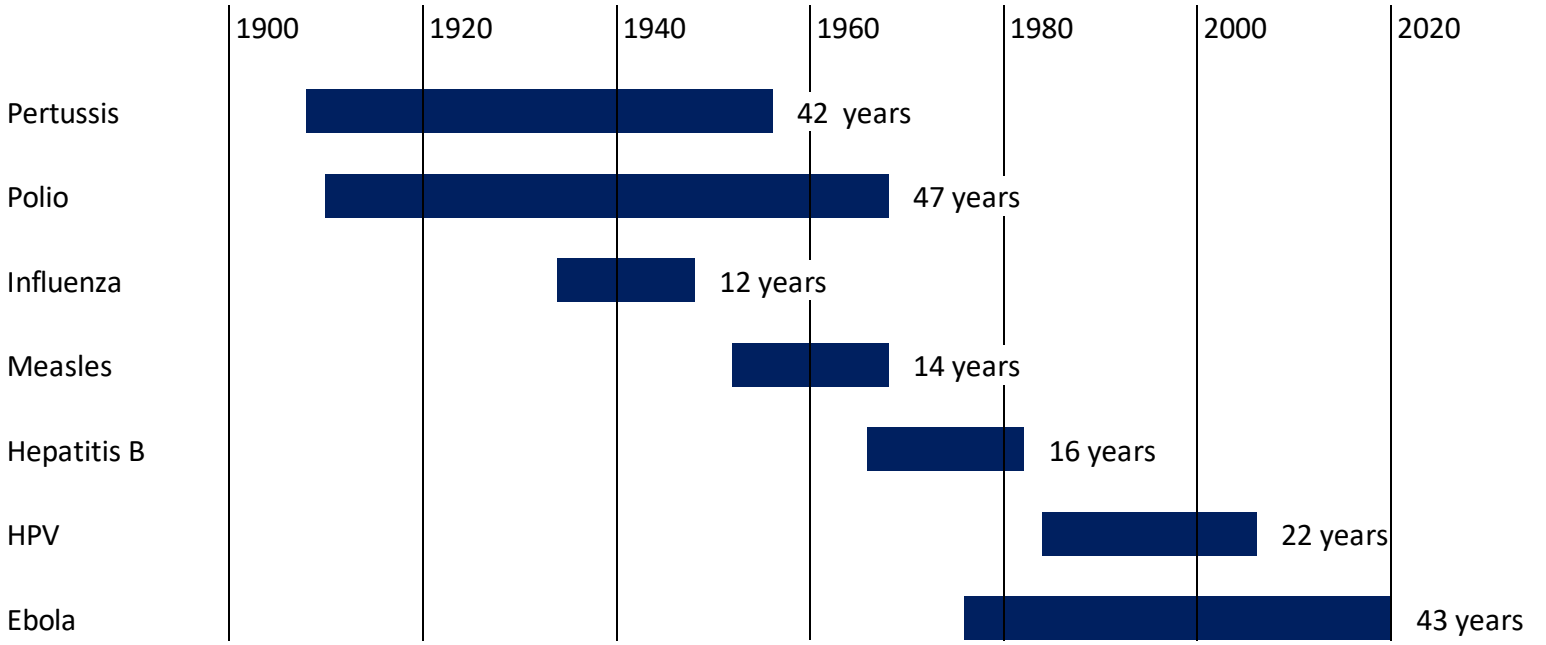
Covid-19 Vaccine Development Process

- AstraZeneca and Johnson & Johnson (JNJ) each received permission to re-start their Phase 3 Covid-19 vaccine clinical trials
- There are now twelve potential vaccines in Phase 3 clinical trials, four of which are being conducted in the U.S. (AstraZeneca, JNJ, Moderna and BioNTech/Pfizer). The twelve clinical trials anticipate > 432k volunteers
- The U.S. trials are are pace for delivering interim results in the next month or so
  - The FDA and CDC recently updated their guidelines for Emergency Use Approval (EUA) and full vaccine approval
  - BioNTech/Pfizer is expected to be first to apply for EUA - sometime in mid-November
- There are at least 145 vaccines worldwide at under development
- The typical vaccine development process takes 10 years and $500M; Based on current expectations, Covid-19 vaccine development could be accomplished in 12-18 months (Q2-Q4 2021 availability)
- Operation Warp Speed (OWS) is a multi-agency effort by the U.S. government to accelerate the vaccine development process, by de-risking the investment required and funding manufacturing efforts in advance of vaccine approval
- Vaccine rollout faces several potential impediments, including consumer participation and supply chain issues:
  - 1/3 of Americans recently surveyed said they were disinterested or somewhat disinterested in receiving the vaccine
  - Primary reasons for this disinterest were: worry about side effects and doubt about vaccine effectiveness
  - Most of the potential vaccines will require cold chain capabilities (i.e., freezers) at the point of administration
  - The need for vials and syringes will be significant; Under OWS, the government is already funding production of these supplies

Vaccine Development timelines have improved over time

Nevertheless, vaccines for many well-known viruses are far longer that what is hoped for with the Covid-19 vaccine

Vaccine Development Time
Discovery of Cause to Vaccine Development



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There is a well-structured process for developing potential vaccines

This process typically involves 10+ years and >$500M in investment

Often, for each vaccine that ultimately receives approval, 100+ potential vaccines are researched

	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Regulatory Approval
Description	Identify proper antigens	Animal tests of antigen formulation	Test on a small group of people (<100)	Test on a larger group: safety and formulation	Evaluate protection & safety on larger group (0000s)	
Time	2-5 years	2 years	1-2 years	2-3 years	2-4 years	1-2 years
Illustrative # of potential vaccines	100	20	10	5	1	1
Investment	$10-20M		$50-100M		$500M-$1B	

Covid-19 Vaccine Development:

# in Pipeline		89	33	14	12	0

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There are reportedly twelve potential vaccines that have reached the Phase 3 clinical trial stage (ten are listed here)

A few of these, including BioNTech and Moderna are at or near full volunteer participation

Source: PLOS Blogs

Company	Vaccine	Target size	Countries	Single or similar trials	Reaching recruitment target
Johnson & Johnson	Ad26.COV2-S	60,000	Argentina, Brazil, Chile, Columbia, Mexico, Peru, South Africa, USA	Single trial	Months away
CanSino	Ad5-nCoV	45,500	40,000-Pakistan 500 – Russia Other sites unconfirmed	Mostly single trial	Months away
BioNTech/Pfizer	BNT162b1-b3	43,998	Argentina, Brail, South Africa, Turkey, USA (cleared to start in Germany)	Single trial	Less than a month away: 90% recruited
AstraZeneca (Oxford University)	ChAdx1 nCov-19/azd1222 (Covidshield)	54,190	12,390-UK 30,000-USA 10,000-Brazil 1,700-India 100-Russia	3 very different large trials & some small	Largest trial months away: 1 in 10,000 healthcare workers (60% recruited after 4 months)
Moderna	mRNA-1273	30,000	USA	Single trial	Fully recruited
Novavax	NVX-CoV2373	39,000	9,000-UK 30,000-USA	Two trials (one not yet underway	Months away
Sputnik V	Gam-COVID-Vac	43,600	40,000-Russia 100-Belarus 2,000-Venezuela ?-UAE 1,500-India	Mostly single trial	Months away (30% recruited)
Sinopharm	2 BBIBP-CoV	60,300	45,000-Bahrain, Egypt, Jordan, UAE 3,000-Beijing, Argentina 200-Morocco 12,000-Peru ?-Morocco, Serbia ?-Pakistan	Two large trials, several small	Close to 90% recruited
Sinovac	CoronaVac	27,980	13,060-Brazil 13,300-Turkey 1,620-Indonesia ?-Philippines	Two large trials, two small	Trial with 13,060 healthcare workers close (90% recruited) 1 small trial fully recruited; others: months away
Bharat Biotech, Indian Medical Research Council	Covaxin	28,500	India	Single trial	Months away

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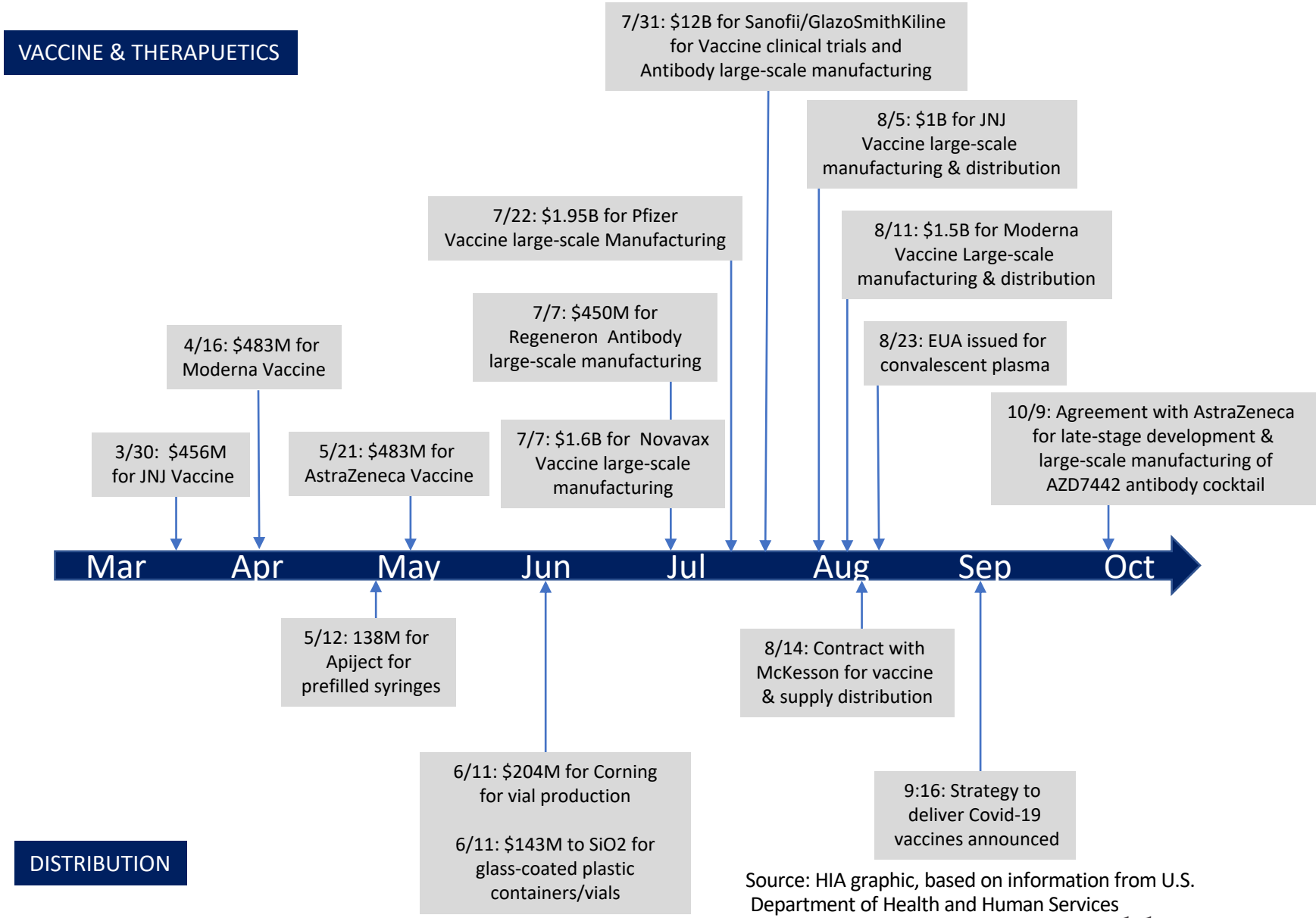
Operation Warp Speed (OWS) is a multi-agency effort of the U.S. government to accelerate the vaccine development and distribution effort

OWS is funding multiple companies, in both vaccine development and manufacturing/ distribution efforts

By de-risking the investment required of the companies, OWS is compressing the timeframe typically required of this process



Source: HIA graphic, based on information from U.S. Department of Health and Human Services

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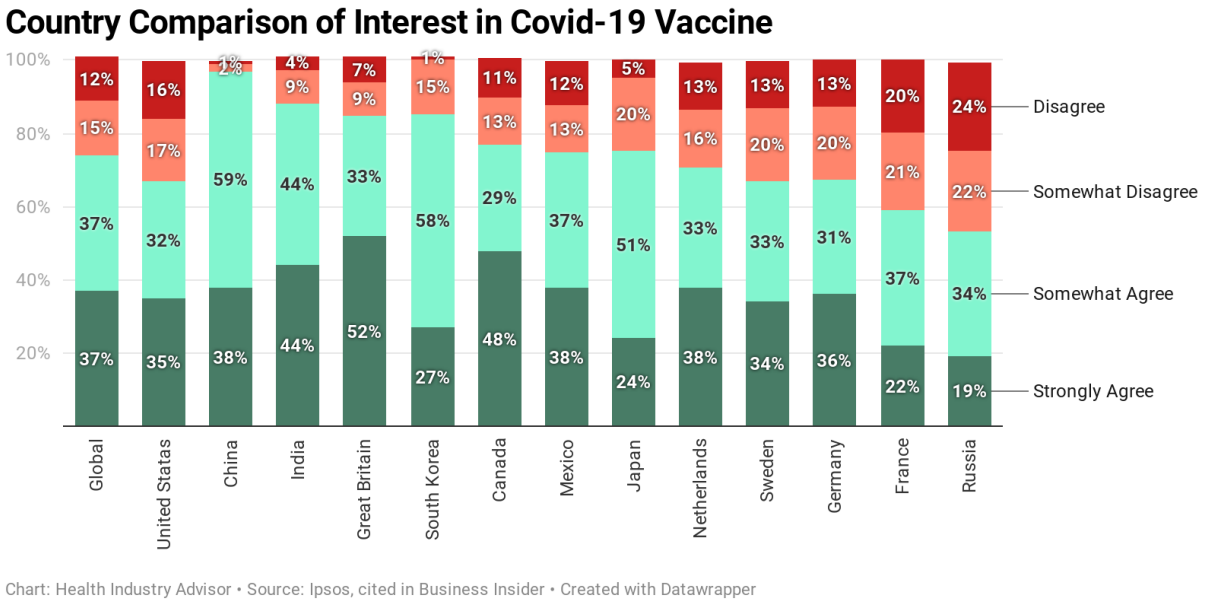
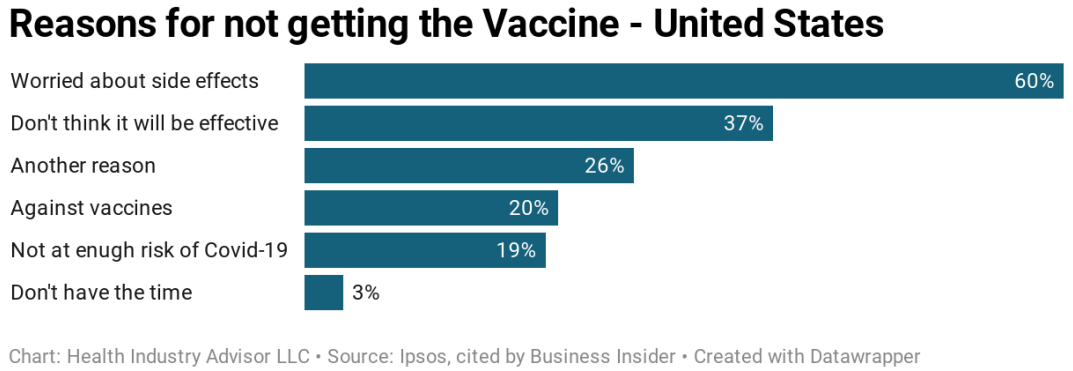
Consumer acceptance of a potential vaccine could be a major impediment to success in reaching herd immunity

In the U.S. 33% of Ipsos survey respondents disagreed or somewhat disagreed with having interest in obtaining the vaccine

Worries about side efforts and vaccine effectiveness drove this resistance; anti-vax concerns, as well as lack of perceived risk from contracting coronavirus were also high on the list





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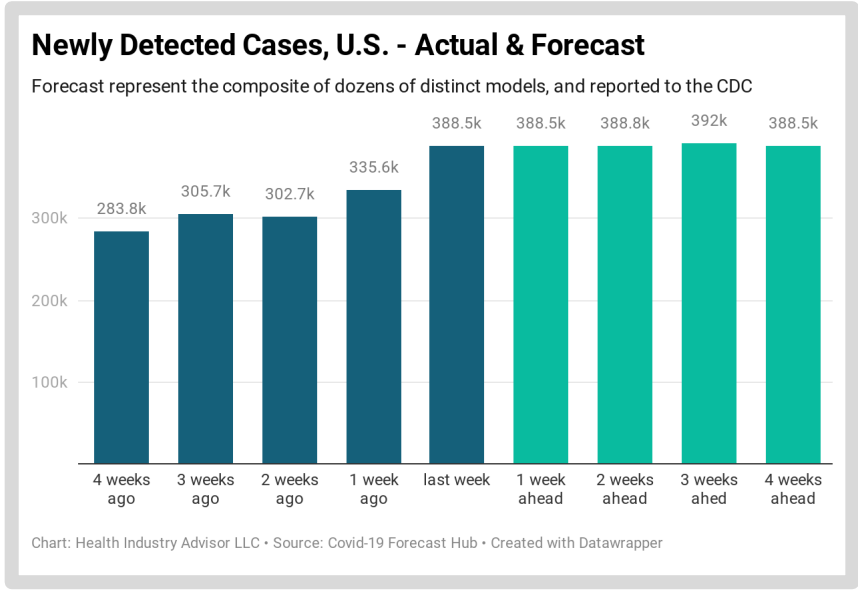
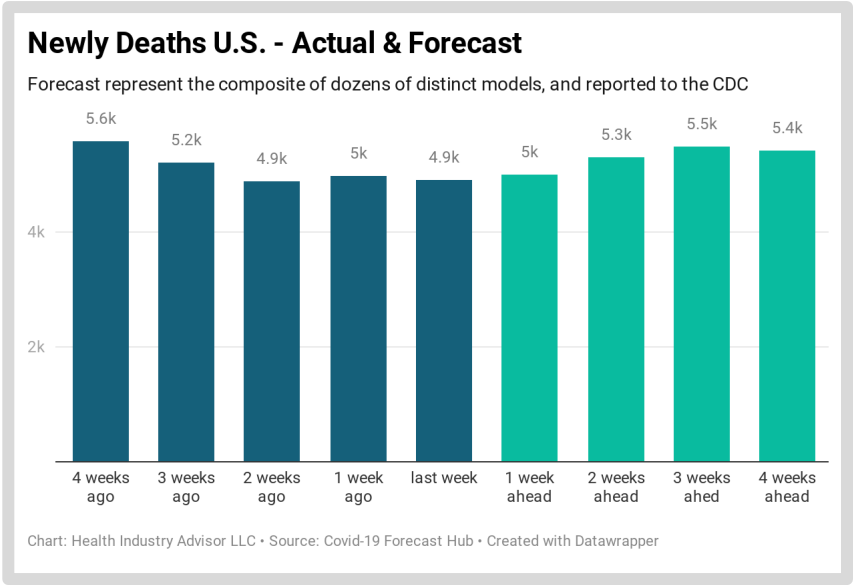
Despite the recent surge in cases and deaths in the U.S., the composite forecast* suggests that both will stabilize over the next four weeks

* Composite of dozens of projections, compiled each Tuesday by Covid-19 Forecast Hub and reported to the CDC





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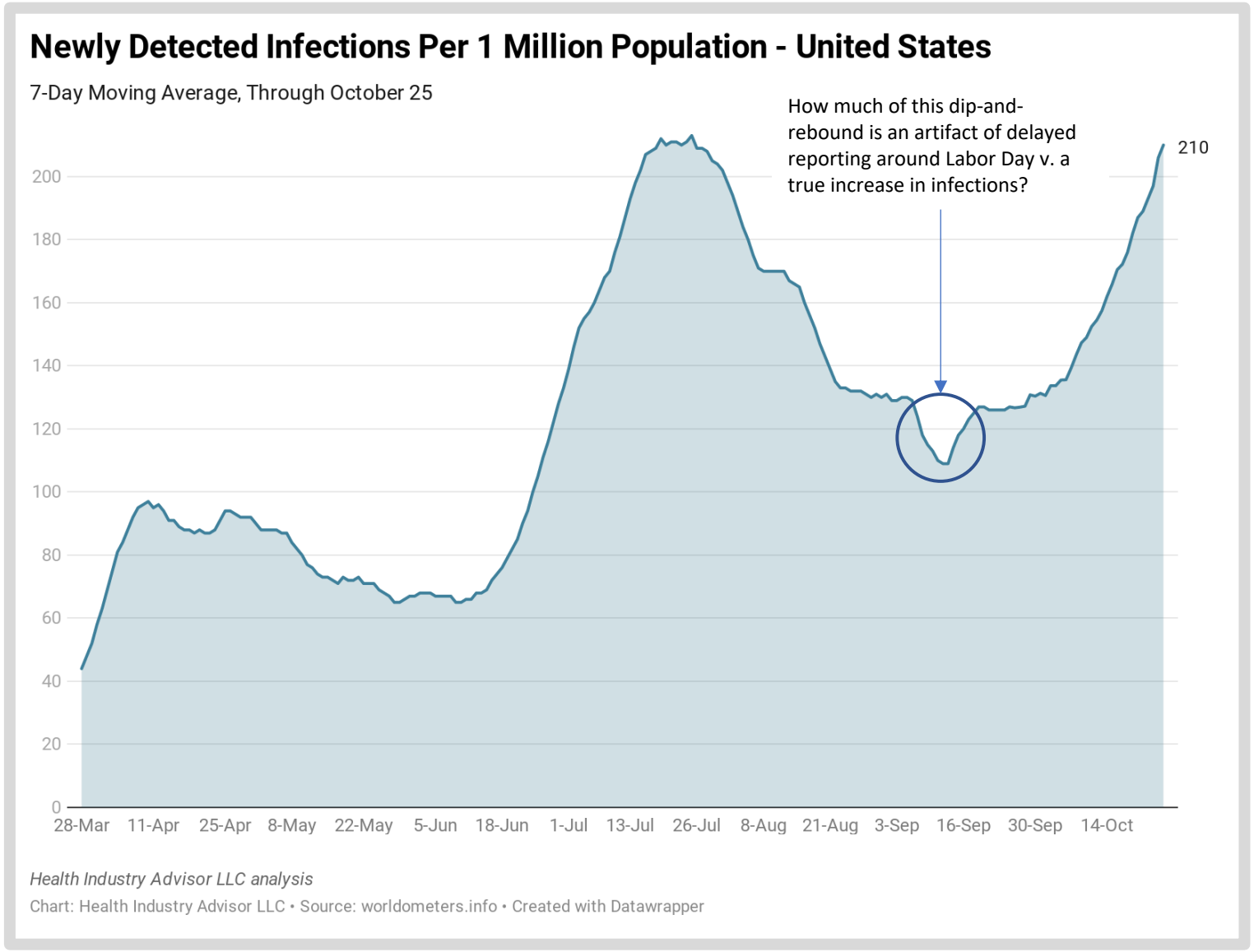
The rate of new infections per capita* in the U.S. rose for the twenty-third consecutive day

This rate is the highest it has been since July 25 and is only fractionally below its peak level, which occurred in late-July

* - 7-day moving average basis



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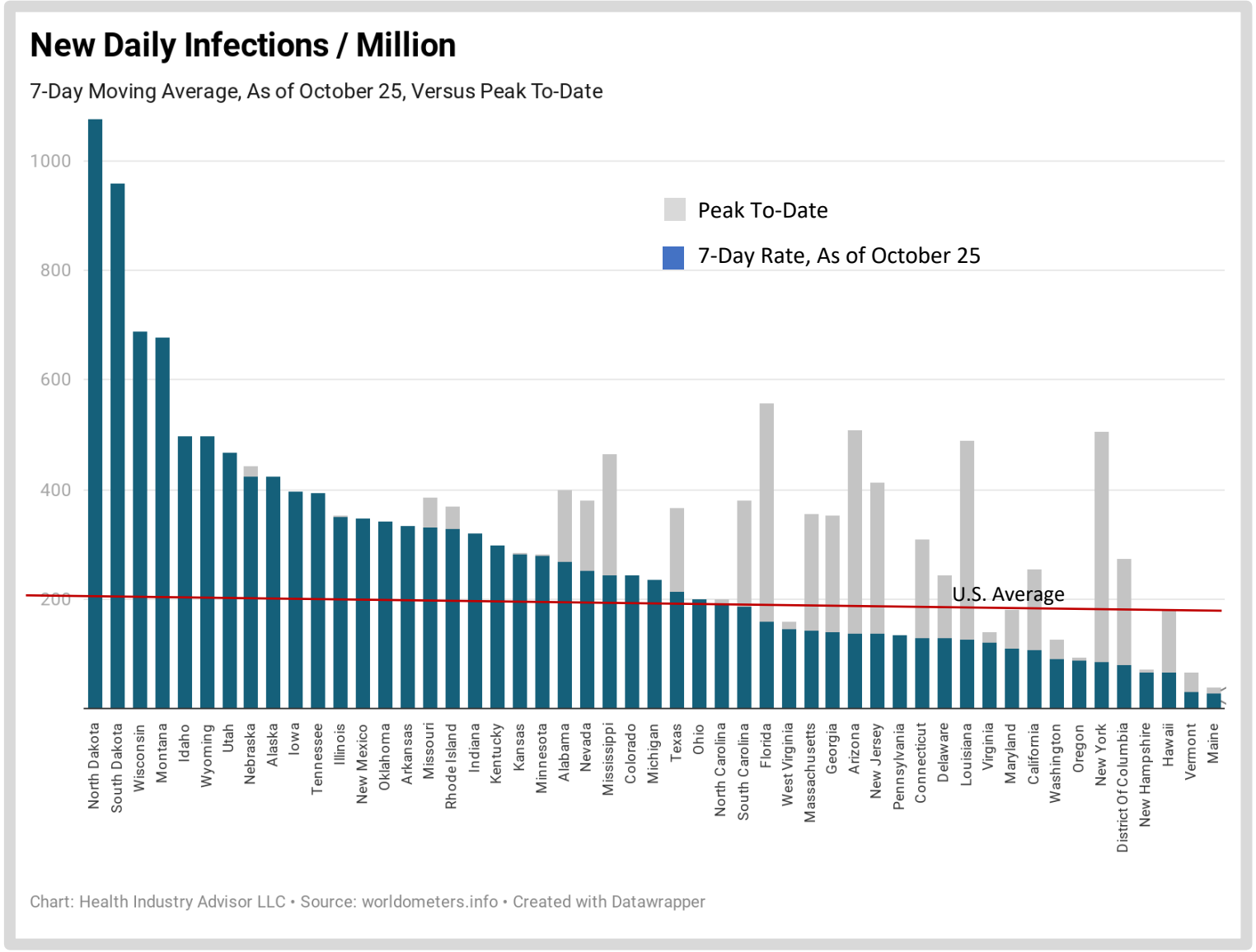
Thirty states are experiencing infection rates at or near the highest level they have experienced to-date

Montana, North and South Dakota and Wisconsin continue to experience the highest rates of new infections per capita*

The current rates in these states are each higher than the highest level experienced in any other state during the pandemic

* - 7-day moving average basis



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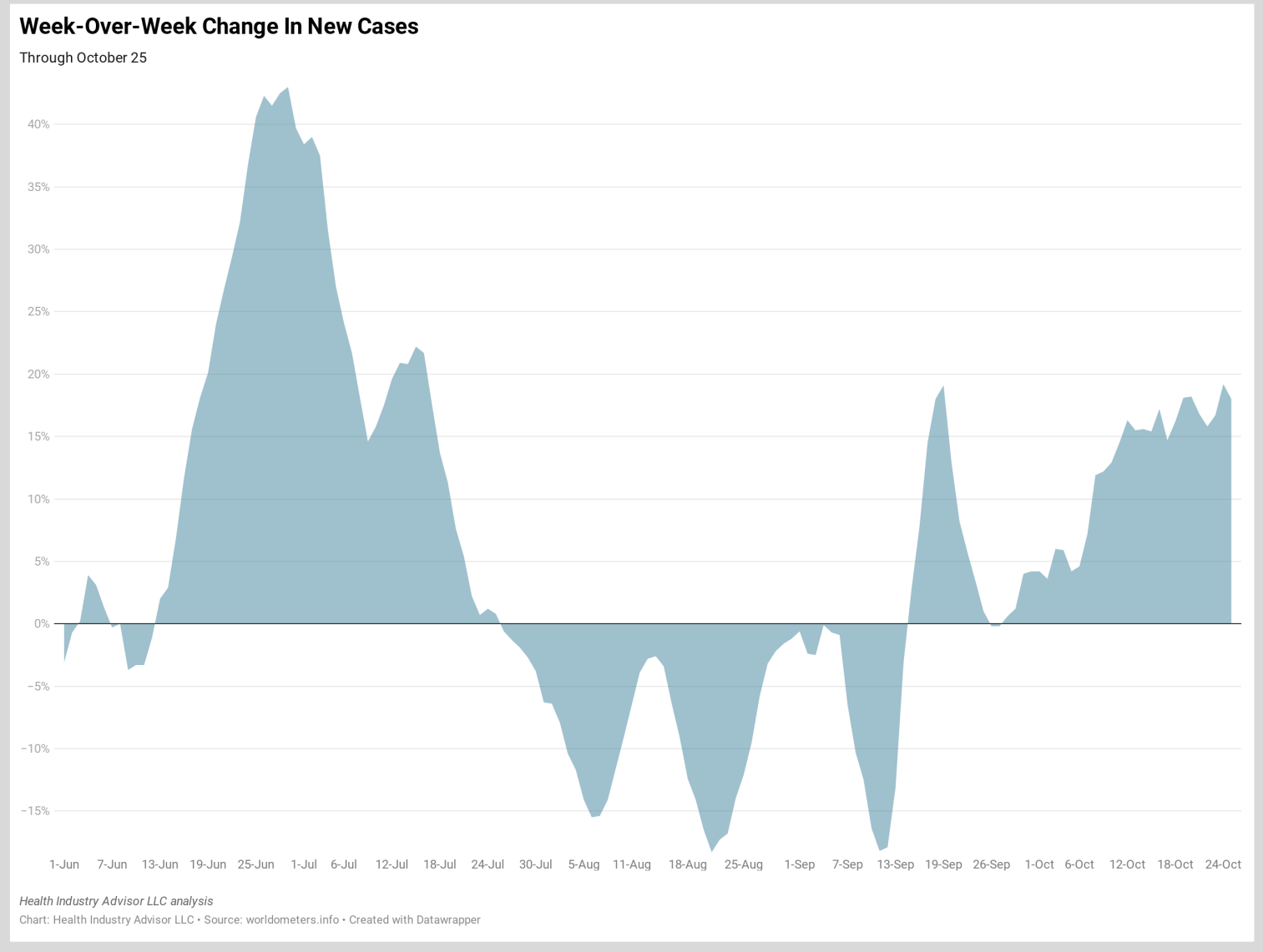
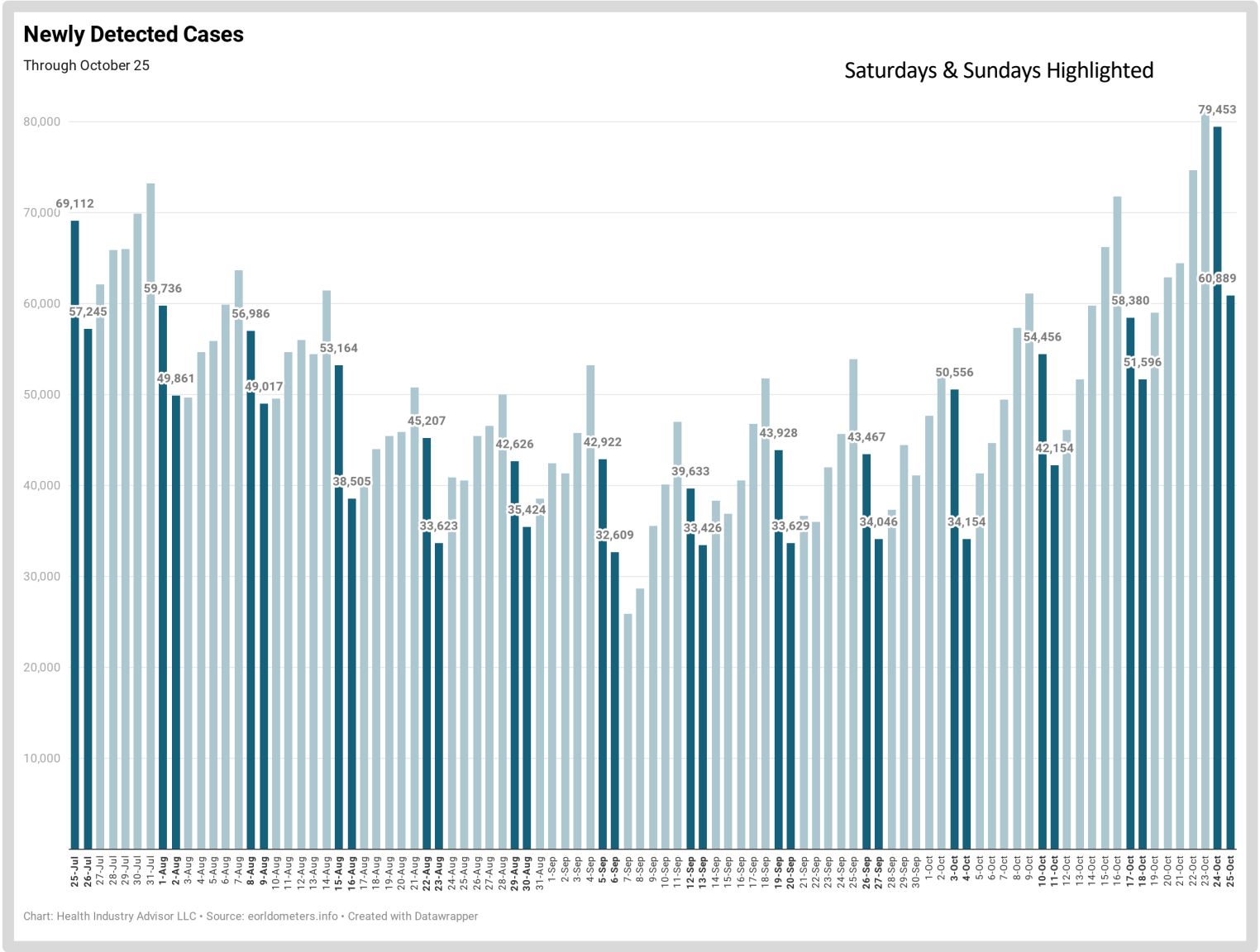
Following a seven-week period of decline, new cases began increasing on a week-over-week basis on September 15

Yesterday, this rate was up 18% on a week-over-week basis; Before this past weekend, it had bounced between 15.2-17.2% for nearly two weeks

This rate had previously peaked at 19.1% on September 19 and 43% on June 29



There were significantly more newly detected cases reported this weekend than on any weekend since the pandemic began



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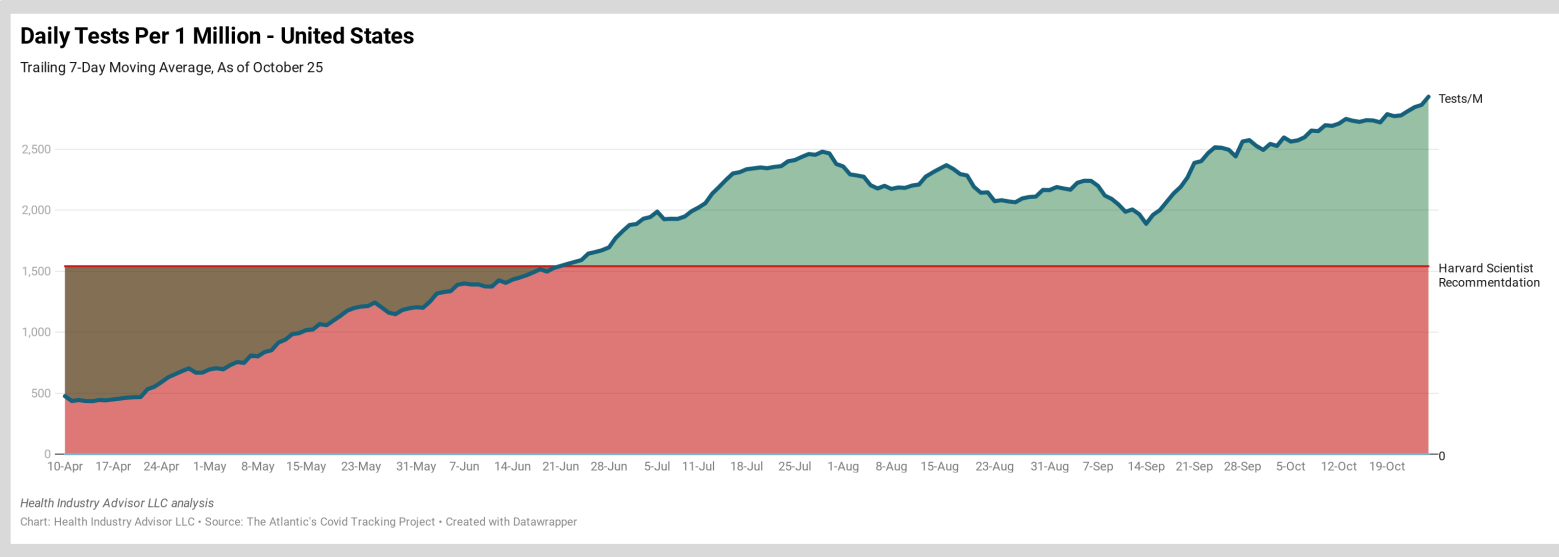
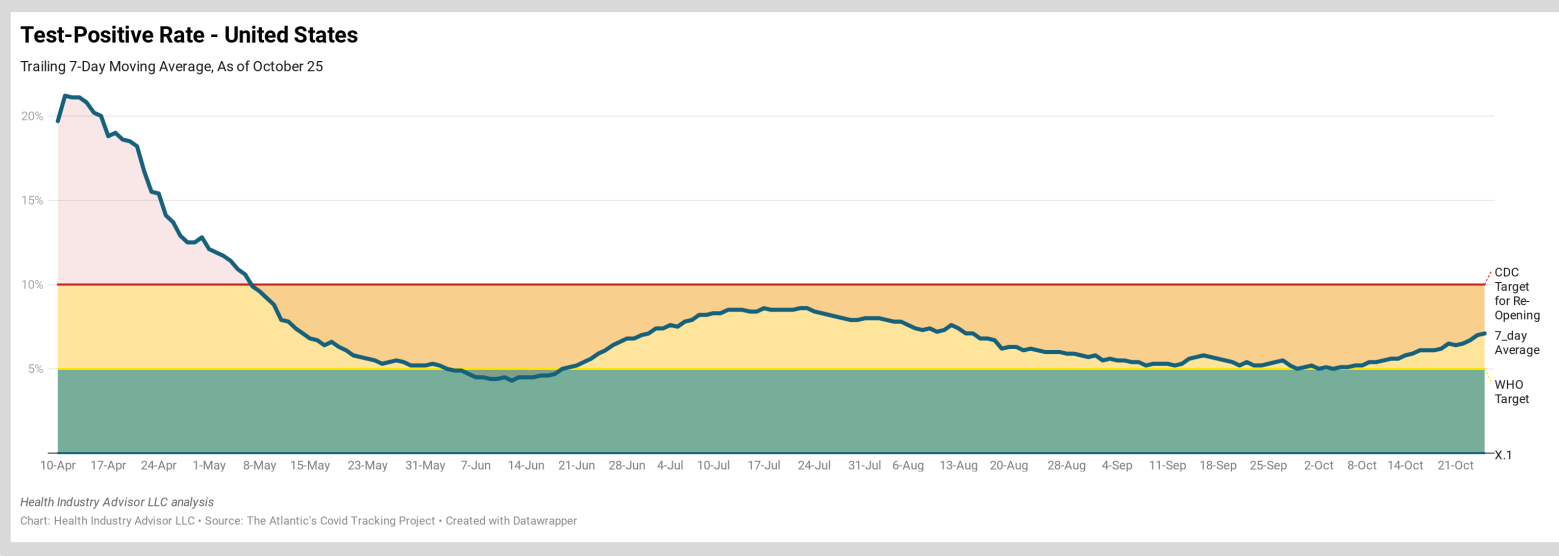
The 7-day average testing volume set another record on Sunday

The 7-day test-positive rate, however, has been trending upward since the beginning of October; It is now higher than it has been since August 15

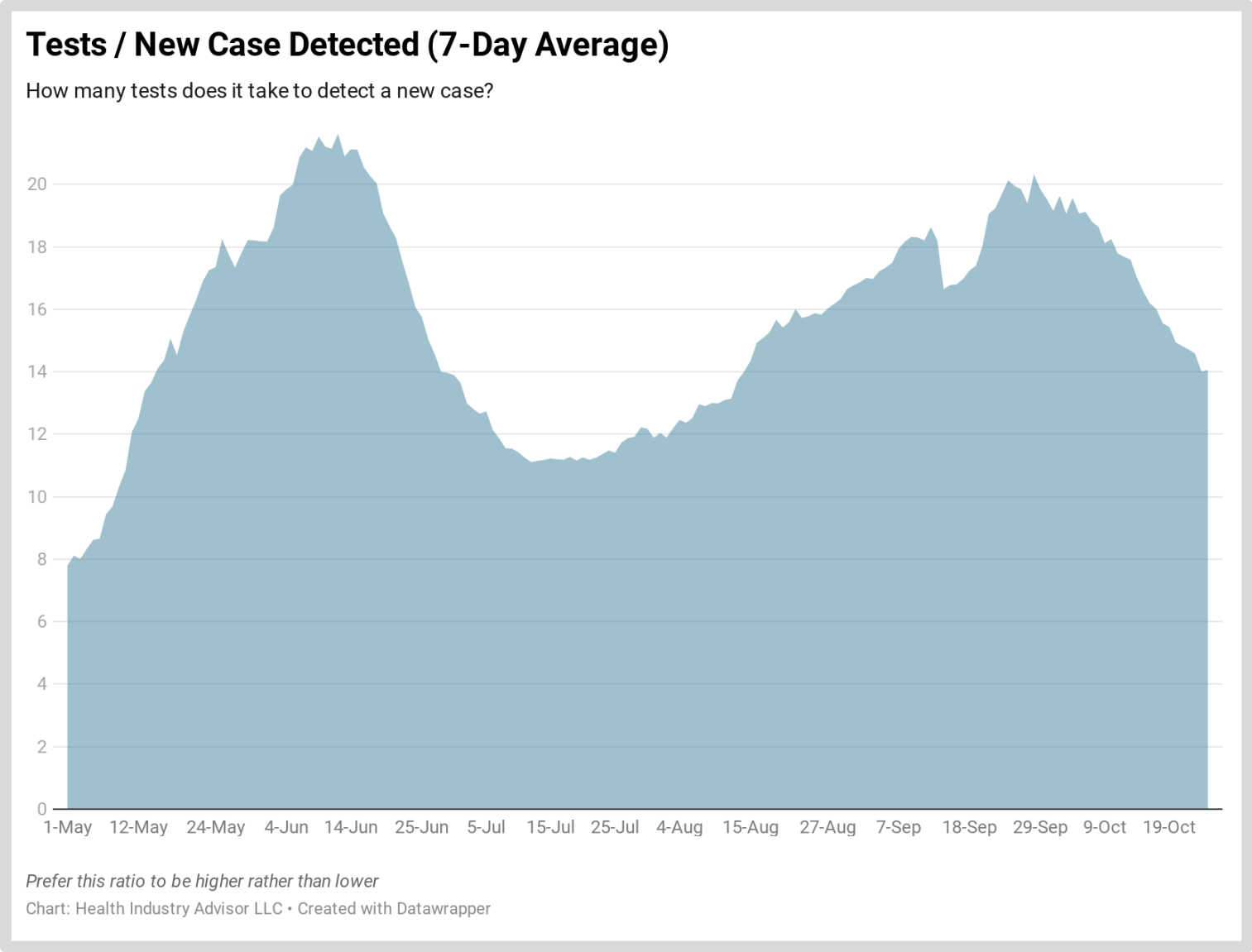




A measure of the effectiveness of testing is the ratio of tests performed to newly-detected cases

This ratio has been declining for the past month – perhaps, testing is not keeping up with the surge in new infections

This rate is now lower than it has been at any time since August 14



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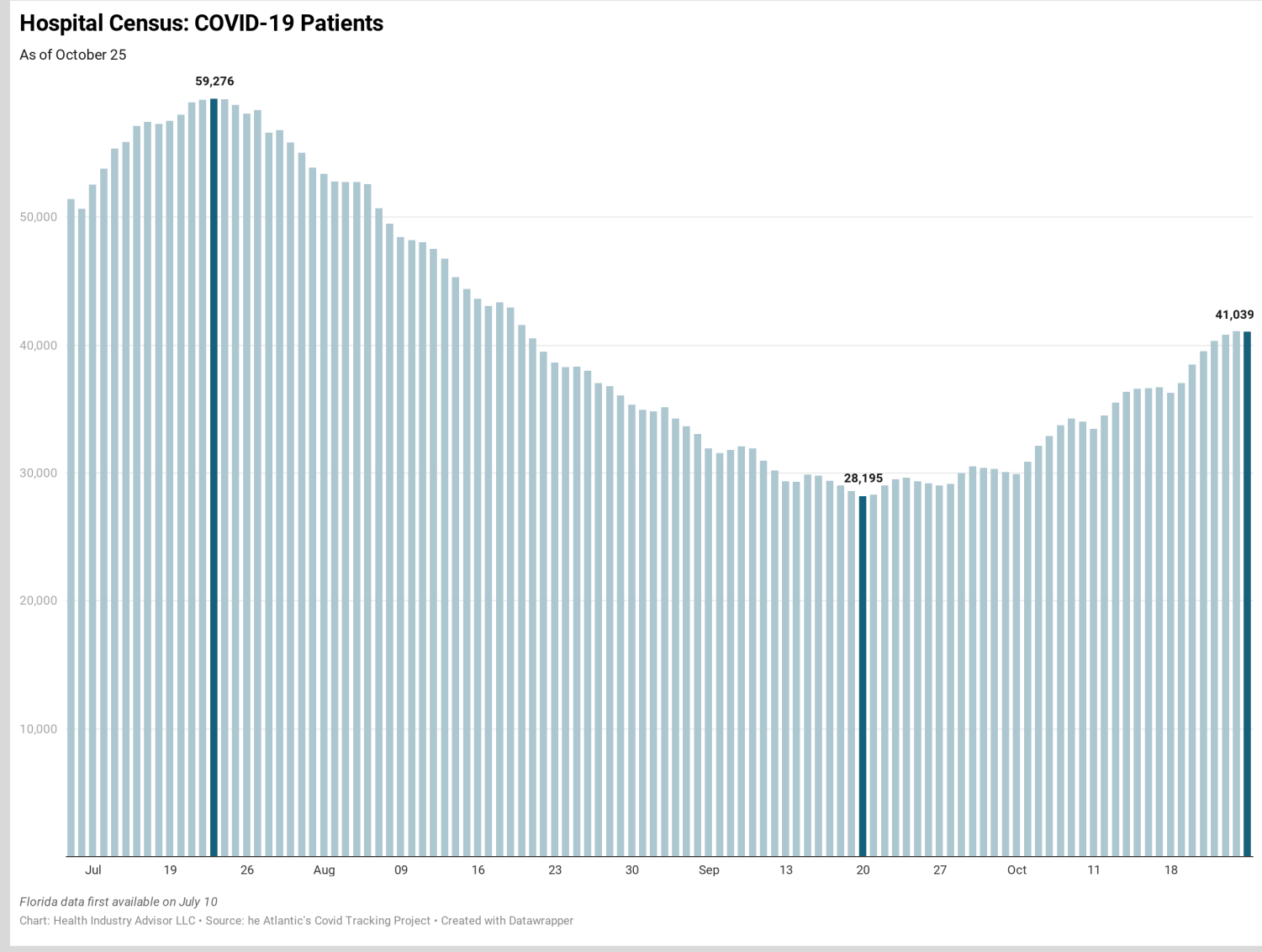
On a same-day, prior-week basis, inpatient Covid-19 census increased for the 32nd consecutive day

This census is 69% of what it was at its peak in late-July yet, has re-gained 41% of the reduction in realized from late-July to September 20



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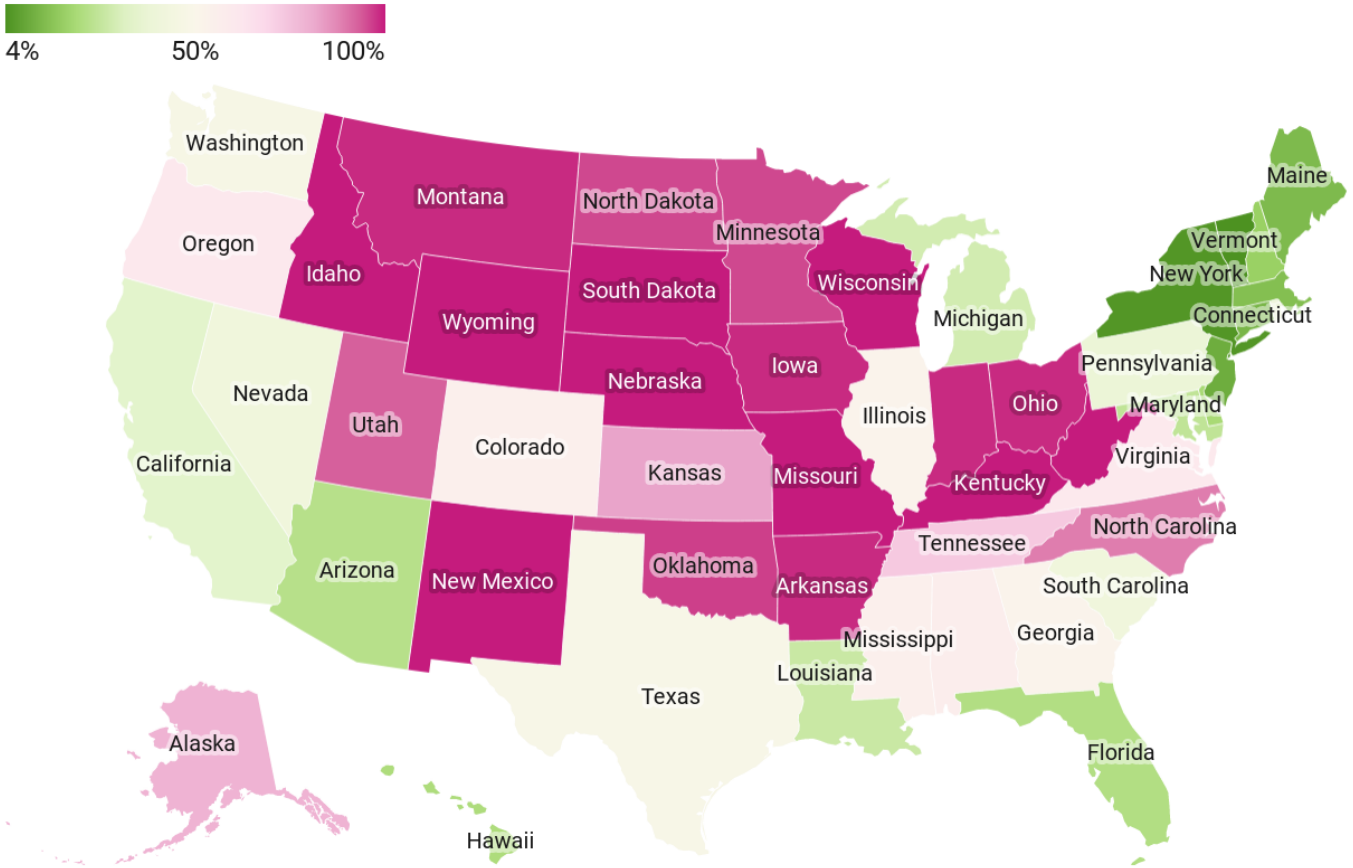
A significant number of states are at or near the highest Covid-19 census experienced at any time during the pandemic

Among heavily-populated states, Ohio is at its highest Covid-19 census; other heavily-populated states are significantly below their highest census

Current 7-Day Covid-19 Inpatient Census v. Peak

As of October 25



Map: Health Industry Advisor LLC • Source: The Atlantic's Covid Tracking Project • Created with Datawrapper

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Note that, while Covid-19 hospital census moves up-and-down with newly-detected cases, the impact of new cases on Covid-19 census has diminished over time

While hospitalizations trended down consistent with new cases in August/September, hospitalizations have not increased at the same rate as new cases in October

Daily New Detected Cases v. Covid-19 Hospital Census

As of October 25

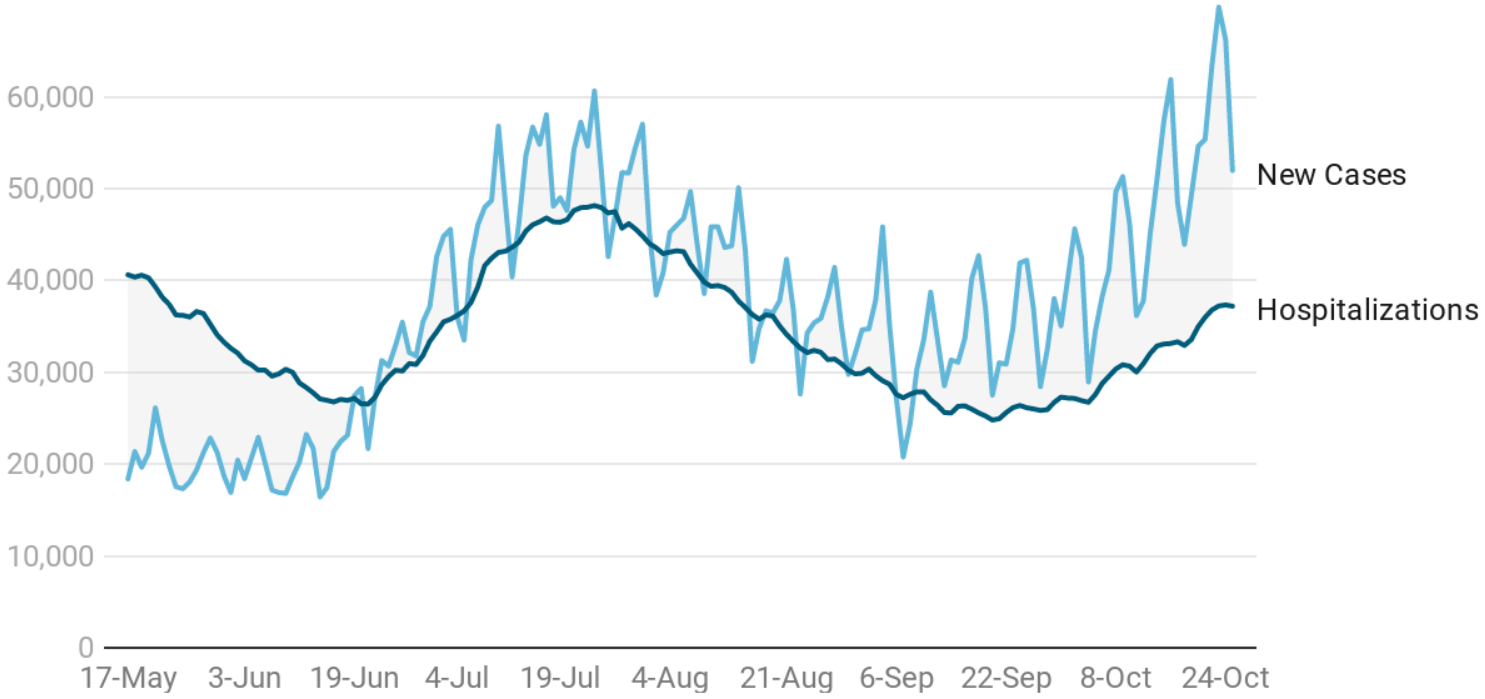

Chart: Health Industry Advisor LLC • Source: The Atlantic's Covid Tracking project & worldometers.info • Created with Datawrapper

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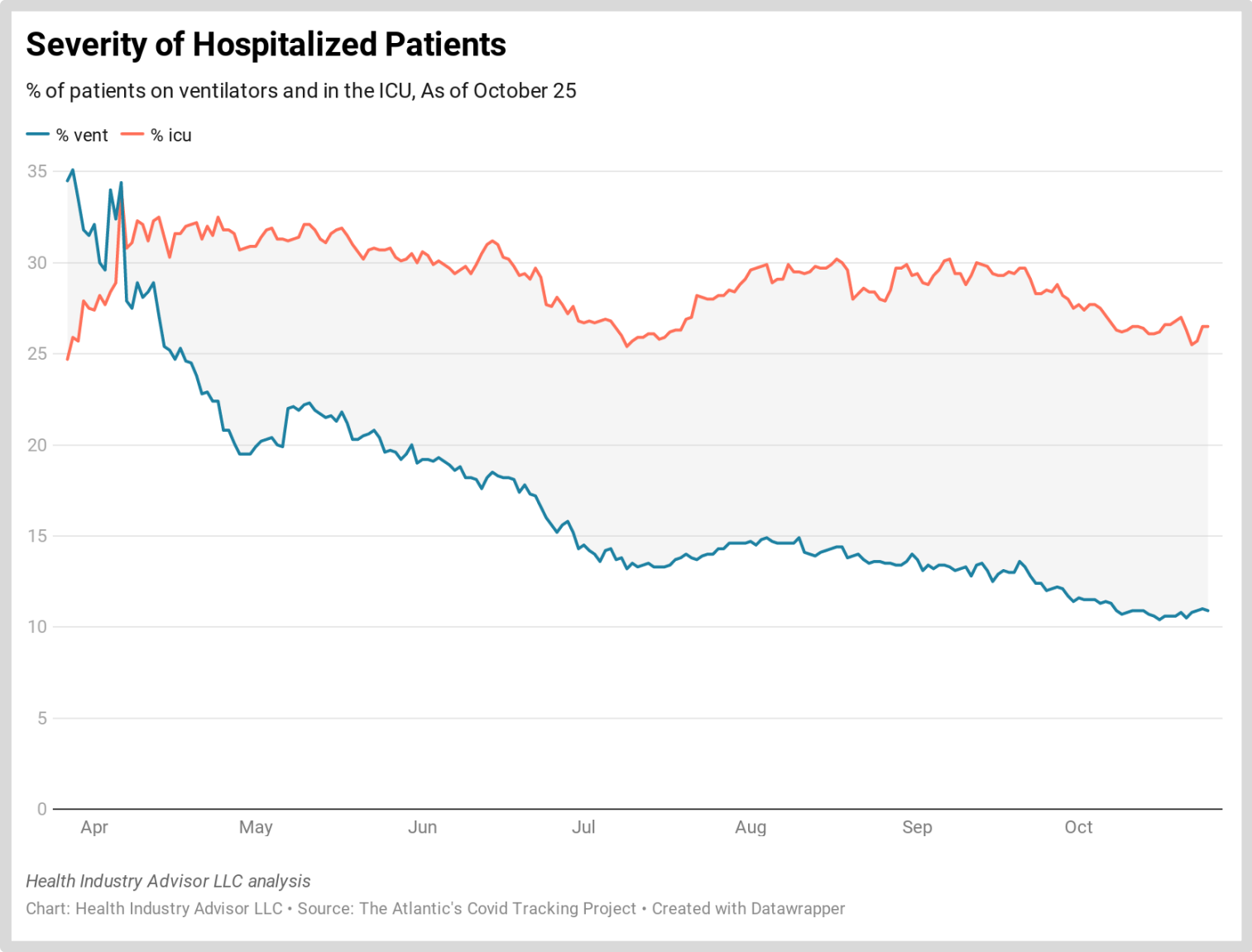
During the recent rise in Covid-19 inpatient census, the % of those inpatients requiring intensive care has declined

The % of Covid-19 inpatients requiring ventilator care has steadily declined since April



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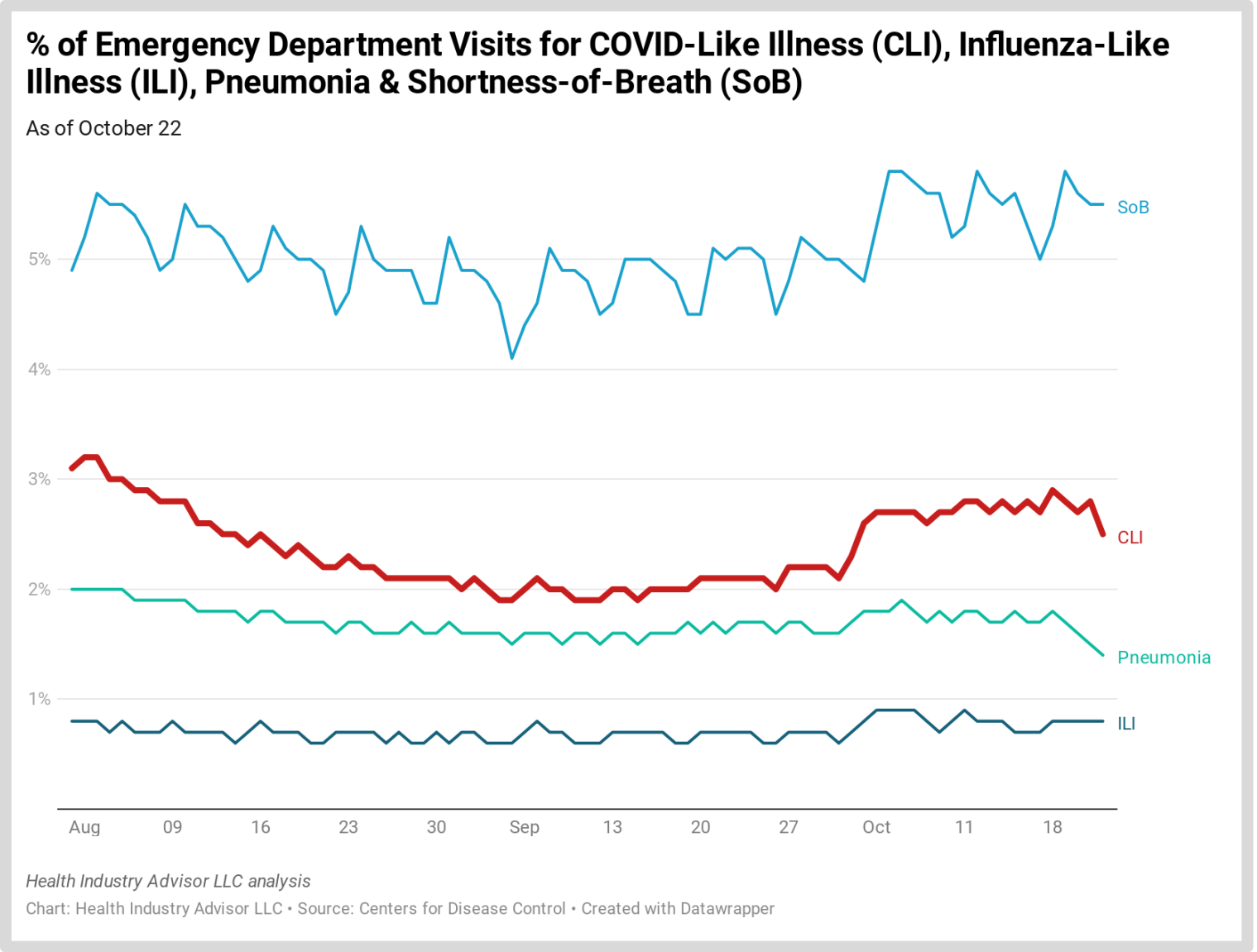
The % of ER visits for COVID-19-like illnesses (CLI) has eased during October; this rate remains significantly lower than it was in mid-July

Although the flu season has officially begun, we have yet to observe any impact on the rate of influenza-like illness (ILI) visits to the ER



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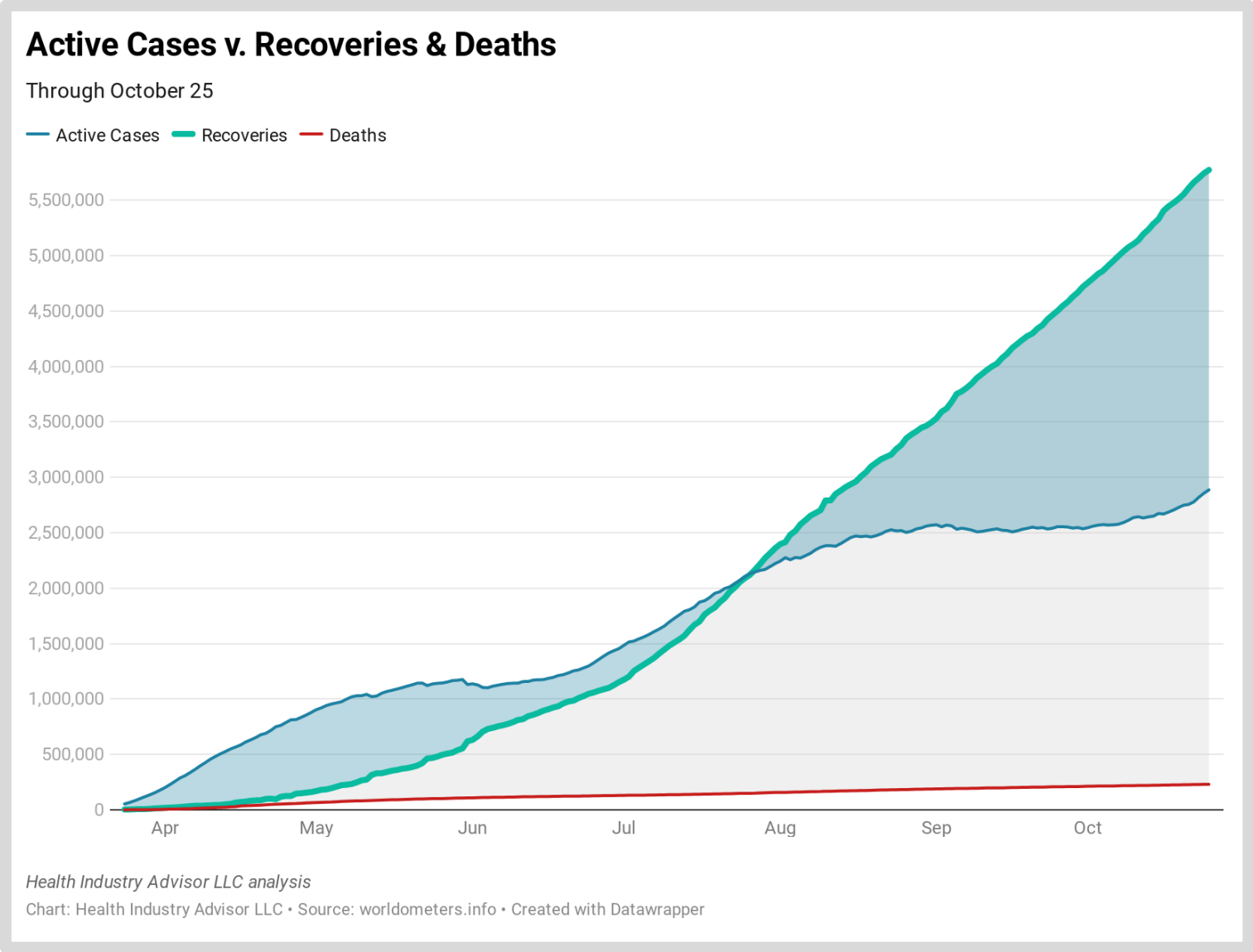
Recoveries from the virus continue to increase

Active cases have increased during the recent surge in new infections



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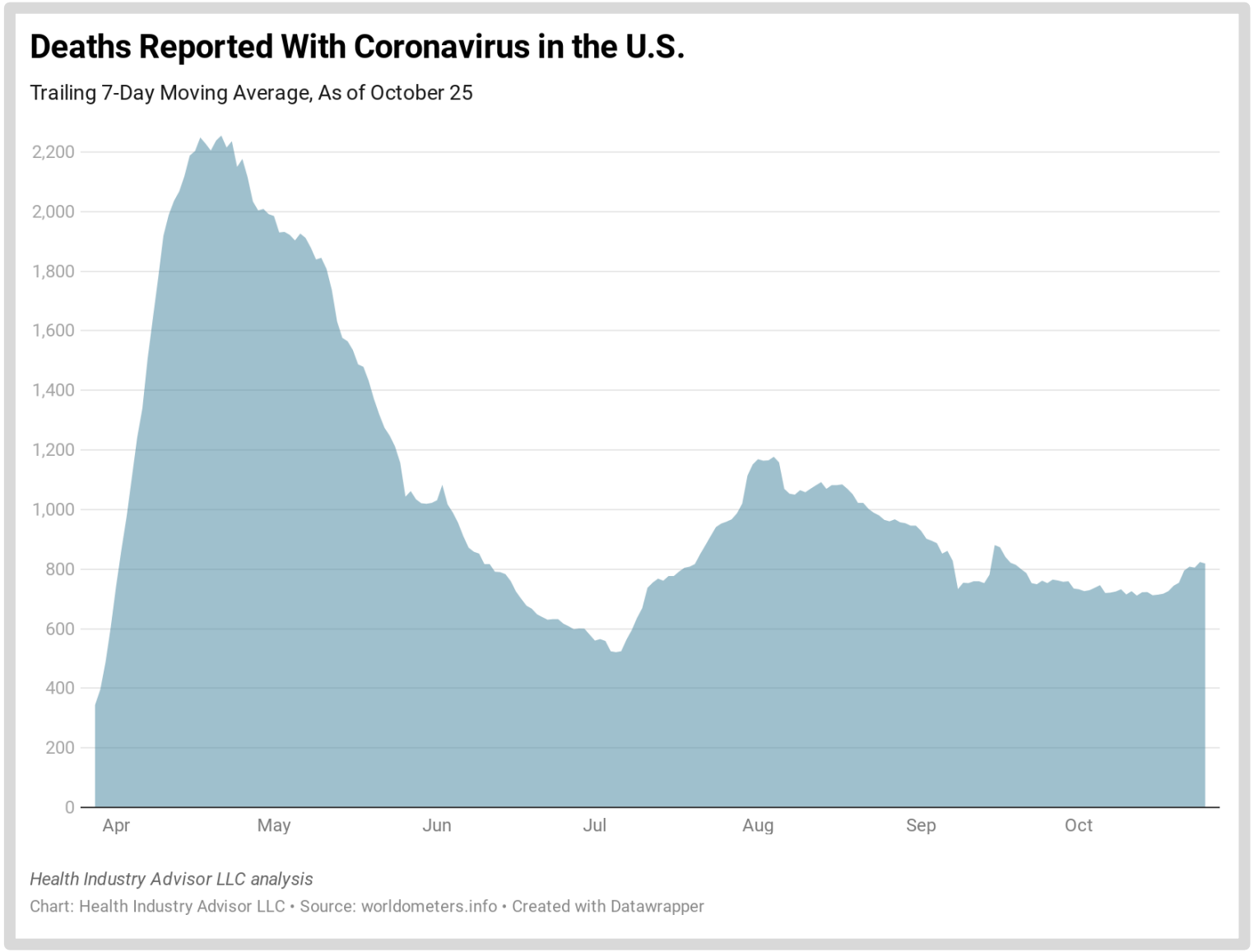
The recent uptick in newly-detected cases is beginning to effect deaths:

The 7-day average deaths per day declined two of the past three days, after increasing on seven consecutive days

Nonetheless, the current rate remains higher than it was from September 19 – October 23



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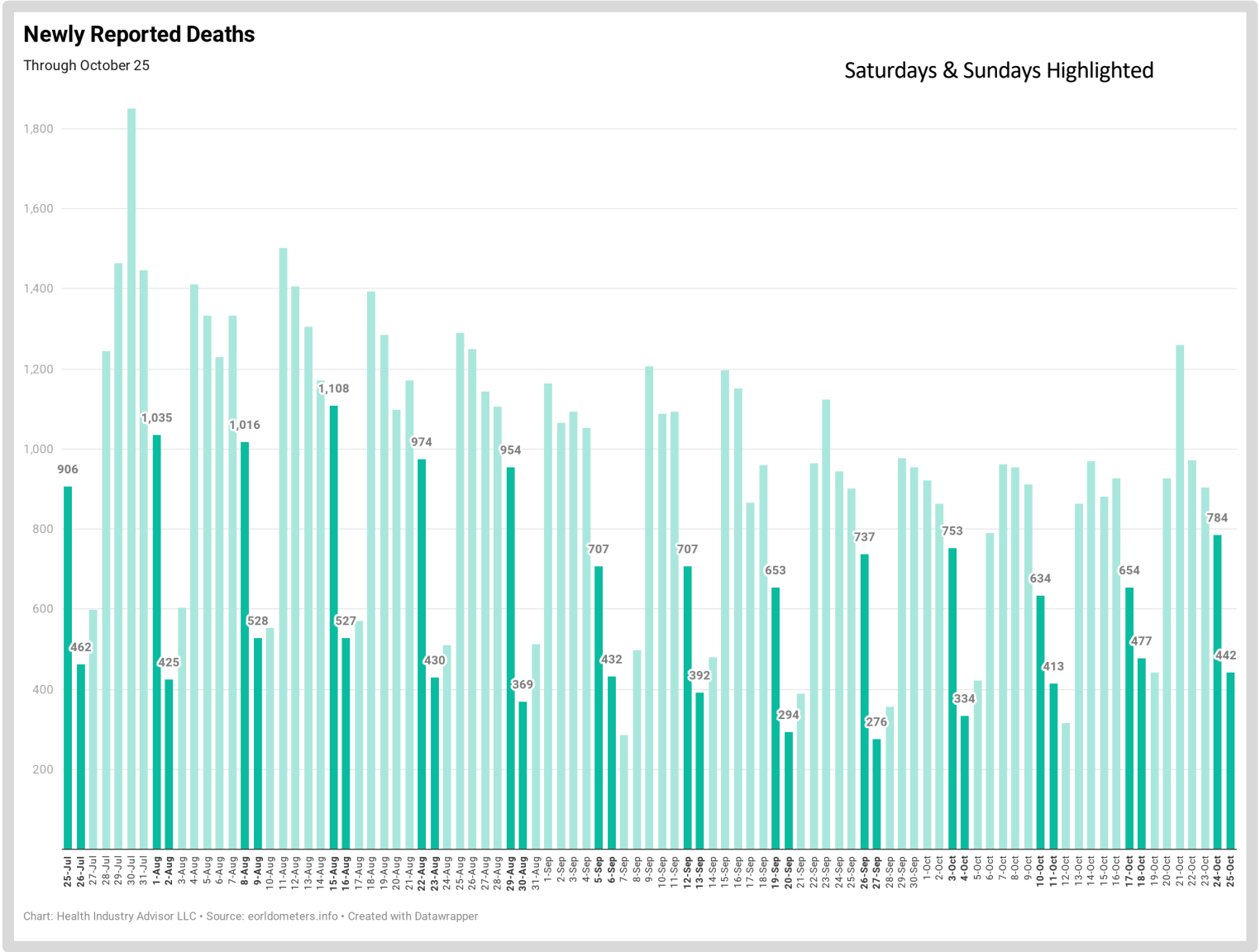
There were more deaths reported this weekend than on weekend since August 29-30



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Data Sources

The following data sources are accessed on a daily or weekly basis:

- The Atlantic's Covid Tracking Project: https://covidtracking.com
- Worldometers.info: https://www.worldometers.info/coronavirus/
- Centers for Disease Control, National, Regional, and State Level Outpatient Illness and Viral Surveillance https://gis.cdc.gov/grasp/fluview/fluportaldashboard.html
- Centers for Disease Control, COVID-19 Laboratory-Confirmed Hospitalizations https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html
- Centers for Disease Control, COVID Data Tracker https://www.cdc.gov/covid-data-tracker/index.html#mobility
- Institute for Health Metrics and Evaluation, COVID-19 estimate downloads http://www.healthdata.org/covid/data-downloads
- New York Times, Covid-19 data https://github.com/nytimes/covid-19-data
- COVID-19 Data Repository by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University https://github.com/CSSEGISandData/COVID-19
- COVID-19 Projections Using Machine Learning, https://covid19-projections.com